WO 2005/046614 PCT/US2004/037810

CLAIMS

We claim:

1. A method for inducing an immunological response against a cell expressing a breast cancer associated antigen in a human, said method comprising the steps of: selecting a human having breast cancer or at risk for developing such a breast cancer tumor, administering to the individual a first vector containing a first gene, or antigenic portion thereof, that encodes a breast cancer associated antigen, and at regular intervals thereafter administering at least a second vector containing a gene encoding a breast cancer associated antigen or antigenic portion thereof, wherein the second vector is from the same or a different source as the first vector.

- 2. The method of claim 1 or 2, further comprising administering at least one costimulatory molecule.
- 3. The method of claim 1 or 2, further comprising administering granulocyte-macrophage colony stimulating factor (GM-CSF).
- 4. The method of claim 2, wherein the co-stimulatory molecule is administered as a gene contained within the same vector as the vector containing gene encoding the breast cancer associated antigen.
- 5. The method of claim 2, wherein the vector contains at least B7.1, LFA-3 and ICAM-1 as co-stimulatory genes.
- 6. The method according to claims 1-5, wherein said breast cancer associated antigen, or antigenic portion thereof, is contained in a pox virus vector.
- 7. The method according to claim 7, wherein said pox virus vector is selected from the group consisting of: an orthopox virus vector; avipox virus vector; a suipox virus vector; a capripox virus vector; a leporipox virus vector; and an iridovirus vector.
- 8. The method according to claim 6, wherein at least one of said pox virus vector is a replication impaired or non-replicating pox virus vector.
- 9. The method according to claim 7, wherein said first pox virus vector is an orthopox vector.
- 10. The method according to claim 9, wherein said orthopox virus vector is Wyeth vaccinia, MVA or NYVAC.

WO 2005/046614 PCT/US2004/037810

11. The method of claims 1-10, wherein the breast cancer associated antigen is selected from the group consisting of carcinoembryonic antigen, mucin, HER-2/neu, uPA, NY-BR-1, NY-BR-62, NY-BR-85, antigenic portions thereof, and modified versions thereof.

- 12. The method of claim 11, wherein the mucin is MUC-1.
- 13. The method of claim 11, wherein the modified version thereof is a wobbled MUC and contains five to fifteen tandem repeats.
- 14. The method of claims 1-11, wherein the vectors contain genes encoding at least two breast cancer associated antigens or antigenic portions thereof.
- 15. The method of claim 14, wherein the breast cancer associated antigens are CEA and a mucin.
- 16. The method of claim 15, wherein the mucin is a wobbled MUC-1 or a wobbled mini-MUC-1 having six tandem repeats.
- 17. The method of claims 1-16, wherein one to three administrations at set intervals are made by an orthopox vector containing the at least one breast cancer associated antigen or antigenic portion thereof and multiple administrations at set intervals are made by an avipox vector containing the at least one breast cancer associated antigen or antigenic portion thereof.
- 18. The method of claim 17, wherein the orthopox vector is vaccinia.

. 1

- 19. The method of claim 18, wherein the vaccinia is vaccinia Wyeth or an attenuated vaccinia.
- 20. The method of claim 19, wherein the attenuated vaccinia is MVA or NYVAC.
- 21. The method of claims 17, 18, 19 or 20, wherein the orthopox vector is administered before the avipox vector is administered.
- 22. The method of claim 21, wherein the set interval is 20 days to 90 days.
- 23. A kit for enhancing a protective immune reaction against a breast cancer tumor comprising at least one pox vector encoding at least two breast cancer associated antigens or antigenic portion thereof.
- 24. The kit of claim 23, wherein one breast cancer associated antigen is CEA and the at least second breast cancer associated antigen is a wobbled MUC-1 or a wobbled mini-MUC-1.